

REMARKS/ARGUMENTS

Claims 1, 4-5, 13-16, 19, 29 and 30 have been amended. Claims 2, and 24-28 were previously cancelled. Claims 6 and claims 29-33 are currently canceled. Accordingly, claims 1, 3-5, and 7-23 are currently pending. Claims 1 and 19 have been amended to indicate that more than one cycle of therapy is administered. Claim 1 has further been amended to indicate that one or more cancer therapeutics is also administered (moving in claim 6 into claim 1).

Claim rejections under 35 U.S.C. §102(b) or §103

The Examiner has maintained the rejection of claims 29-33 under 103(a) as being unpatentable over Webb et al. (The Lancet, 1997 vol. 349:1137-1141) in view of Bennett et al. (U.S. Patent 6,214,986). Applicants have canceled these claims, thus rendering this ground of rejection moot.

Claim rejections under 35 U.S.C. §112

Applicants respectfully submit that the present claim amendments render this ground of rejection moot and accordingly request withdrawal of this ground of rejection.

Claim rejections under 35 U.S.C. 103

The Examiner has rejected claims 1, 3-5, and 13-18 under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (The Lancet, 1997 vol. 349:1137-1141) in view of Waters et al. (Journal of Clinical Oncology, 2000 Vol. 18:1812-1823).

The Examiner notes that Webb does not teach each cycle of therapy separated by an interval of time wherein the human receives no bcl-2 antisense oligonucleotide, and further does not teach or suggest the claimed composition to be used in the recited treatment of regimen. However, the Examiner has argued that it would have been obvious to take the teachings of Webb and Waters and arrive at the present invention.

Applicants disagree and respectfully assert that the Examiner has impermissibly used hindsight to arrive at the claimed invention. Applicants have obtained a Declaration from Dr. Steven Craig Novick, which is attached hereto. In this Declaration, Dr. Novick points out that in his opinion the reference only teaches a two-week treatment regimen.

See Declaration, paragraph 10. Dr. Novick also points out that there is nothing in Webb that would teach or suggest to one skilled in the art to treat a patient for cancer by shorting the regimen to less than the two-week course of treatment, let alone shorten the course of treatment to a cycle of therapy consisting of three to nine days (as is presently claimed in the '170 application). See Declaration, paragraph 11. According to Dr. Novick, one skilled in the art would not be motivated to shorten the course of therapy to treat cancer just because one patient showed reduced bcl-2 levels at week 1 and week 2, especially since patient 6 only showed a partial or negligible tumor response (page 2, column 1139). See Declaration, paragraphs 12-14. Dr. Novick concludes that Webb does not teach or suggest changing the treatment regimen to anything shorter than a two-week course of therapy, let alone to a three to nine day course of therapy as presently claimed in the '170 application. See Declaration, paragraph 15.

Regarding the Waters reference, Dr. Novick concludes that it only teaches a course of therapy for two weeks. See Declaration, paragraph 16. Dr. Novick also states that just because toxic events in certain patients caused the treatment with bcl-2 antisense oligonucleotide to be discontinued there is no teaching or suggestion to use a shorter course of therapy to treat cancer. See Declaration, paragraph 17.

Dr. Novick also notes that just because Waters reports that certain patients had adverse effects and had their course of therapy terminated, this is no way teaches or suggests using a shorter course of therapy. For example, Patient 15's treatment was discontinued on day one, Patient 16's treatment was discontinued on day 12 and Patient 17's treatment was discontinued after day 2 (48 hours). Dr. Novick points out that, even if one skilled in the art would be motivated to shorten the cycle of therapy to treat cancer, there is nothing in this data to teach or suggest shortening the cycle of therapy to three to nine days, separated by an interval of time when the therapy is not given and repeating with another three to nine day cycle of therapy (as the current pending claim requires). See Declaration, paragraph 18. Concurring with Dr. Novick, applicants assert that it is clear that patients 15, 16 and 17 did not receive a course of therapy from three days to nine days, separated by a time of not receiving therapy and then receiving another course of therapy from three to nine days, as required by the pending claims.

Dr. Novick also points out that even with Patient 17 only receiving 2 days of treatment followed by another course of therapy (since Waters reports that patient 17 received a second course of therapy), Waters still does not teach or suggest the claimed method of treating cancer where the patient is given a course of therapy of three to nine days, followed by a rest period, followed by another three to nine day course of therapy. First, patient 17 only received a two-day dose of therapy as Waters states that treatment was discontinued after 48 hours. Dr. Novick further concludes that there is nothing to teach or suggest that Patient 17's second course of therapy was anything but the 14- day cycle of the planned treatment protocol. There is therefore nothing in Waters to teach or suggest the invention as claimed, let alone teach or suggest a second cycle consisting of three to nine days. See Declaration, paragraph 19.

Regarding Patient 18, Dr. Novick points out that the treatment was discontinued at day 8. However, he notes there is nothing in article that states that Patient 18 went onto receive a second course of therapy. Waters mentions that only three patients (Patient 2, 17 and 21) received a second course of therapy. Waters does not teach or suggest that it was Patient 18 and in fact clearly indicates by deduction that it was not Patient 18. *See* page 1813, first col. and page 1818, first col. Thus, Dr. Novick concludes that there is no teaching or suggestion to shorten the course of therapy from 14 days to three to nine days and then continue on with another course of therapy of three to nine days after a rest period between. See Declaration, paragraph 20.

Thus, Dr. Novick concludes that there is nothing in Webb or Waters to teach or suggest a cycle of therapy to treat cancer consisting of three to nine days, followed by an interval of time where no bcl-2 antisense oligonucleotide is administered, followed by another three to nine day cycle of therapy (as required by the claims of the instant application). See Declaration, paragraph 22. He further opines that in his opinion one skilled in the art with the knowledge of Webb and Waters, would have not been motivated to treat cancer by shortening the cycle of therapy to from the accepted 2 week cycle of therapy to a cycle of therapy consisting of three to nine days, followed by an interval of time where no bcl-2 antisense oligonucleotide is administered, followed by another three to nine day cycle of therapy. See Declaration, paragraph 21-23.

Applicants therefore submit that the Examiner has taken the present claimed invention and read back into the Webb and Waters reference to find an alleged motivation. This is clearly hindsight, which is impermissible. Accordingly, applicants request withdrawal of this ground of rejection.

Claim rejections under 35 U.S.C. §103(a)

The Examiner has rejected claims 1 and 3-23 as unpatentable over Webb in view of Waters and Bennett. As discussed above, Webb nor Waters do not teach or suggest the claimed invention. Bennett does not cure these deficiencies. As such, applicants request withdrawal of this ground of rejection.

CONCLUSION

Applicants respectfully submit that, in view of the foregoing amendments and remarks, the present application is in condition for allowance. If the Examiner would like to discuss any remaining issues in this application, the Examiner is invited to contact the undersigned at the phone number provided below.

Applicants authorize the Commissioner to charge the requisite fee for the request for continuation examination as well as any other fee due or credit any overpayment arising from this communication to Deposit Account No. 11-0600.

Respectfully submitted,

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